CLAIMS

1. A crystalline, hydrated form of the sodium salt of 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonic acid, wherein the form contains from 6.4 up to 22 weight % of sodium and 15 up to 23 weight % of crystalline water if the sodium content is lower than 7.5 weight %, based on the whole molecule, or 4.5 up to 18 weight % of crystalline water if the sodium content is equal to or higher than 13 weight %, based on the anhydrous substance.

2. The crystalline form according to claim 1, which is pentahydrate of the monosodium salt of 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonic acid, wherein said form contains 20 up to 23 weight % of water built in the crystal lattice and 5.5 up to 7.5 % of sodium, based on the whole molecule.

3. The crystalline form according to claim 2 wherein said form contains 22.8 weight % of water built in the crystal lattice and 6.4 up to 6.7 % of sodium, based on the whole molecule.

4. The crystalline form according to claims 2 or 3 wherein said form shows a powder X-ray diffraction pattern with interplanar distances d approximately 16.3; 13.0; 9.1 and 4.9 Å.

5. The crystalline form according to claims 2 or 3 wherein said form shows the infrared spectrum with bands 1169; 1060; 1046 and 891 cm^{-1}.

6. The crystalline form according to claims 2 or 3 thermogravimetric analysis of which shows a plateau at temperature of about 173 °C.

7. The crystalline form according to claims 2 or 3 the ^{31}P CP-MAS NMR spectrum of which shows signals 13.7 and 20.0 ppm.

8. The crystalline form according to claim 1, which is trihydrate of the trisodium salt of 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonic acid, wherein said form contains

The term risedronate stands for both risedronic acid and its pharmaceutically acceptable salts.

The term risedronate sodium salt monohydrate refers to a crystalline form of monosodium 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonate which contains from 5 to 7.1 w.% of water and from 5.5 to 7.5% of sodium, based on the whole molecule.

The term risedronate sodium salt pentahemihydrate stands for a crystalline form of monosodium 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonate which contains from 11.9 to 13.9 w.% of water and from 5.5 to 7.5% of sodium, based on the whole molecule.

The term risedronate sodium salt pentahydrate stands for a crystalline form of monosodium 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonate which contains from 20 to 23 w.% of water and from 5.5 to 7.5% of sodium, based on the whole molecule.

The term risedronate disodium salt monohydrate stands for a crystalline form of disodium 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonate which contains from 4.5 to 6.5 % of water and from 13 to 15% of sodium based on the anhydrous salt.

The term risedronate trisodium salt trihydrate stands for a crystalline form of trisodium 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonate which contains from 12 to 14 % of water and from 19 to 21% of sodium based on the anhydrous salt.

If not specified otherwise, all the percentage data herein are given in weight percents.

Our invention concerns sodium 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonate (sodium risedronate) in so-far-undocumented crystalline forms. More specifically, they are hydrates which contain 6.4 up to 22% of sodium and simultaneously 15 up to 23% of crystalline water if the sodium content is lower than 7.5%, based on the whole molecule, or 4.5 up to 18% if the sodium content is equal to or higher than 13 weight %, based on the anhydrous substance.

An useful example of such a hydrate is a modification that is characterized by water content 20 up to 23%, specially with 22.8 w.% of water, and sodium content 5.5 up to 7.5%, specially 6.4 up to 6.7 w.%. The specified water content is built in the crystal lattice and the mentioned crystalline modification is thermodynamically stable. By drying with several different drying regimes, the mentioned crystalline modification was dried to the water content corresponding to the pentahemihydrate, the monohydrate and the anhydrous form of sodium 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonate. When the substance is left

standing on the air, the water content stabilizes spontaneously at the original level. Time that it takes for the water content to stabilize depends on relative humidity in the environment in